

### **REMARKS**

As an initial matter, Applicant appreciates the Examiner's thorough examination of the present application. Applicant draws the Examiner's attention that claims 1-9 have been canceled and claims 18-27 have been added to better define the subject matter which Applicant regards as the invention. Each of the amendments to the claims is fully supported in the present application as originally filed. No new matter has been added.

#### **Election/Restrictions**

Applicant acknowledges the final status of the restriction requirement and hereby withdraws claims 10-17 from further consideration to reserve rights to later file a divisional application(s) in the future.

#### **Claim Objections**

Claim 8 has been canceled. Therefore, the objection of claim 8 for having a typographical error is moot.

#### **35 U.S.C. § 101 Rejection**

Claim 5 stands rejected under 35 U.S.C. § 101 for being directed to a non-statutory subject matter. This rejection is respectfully traversed.

Applicant has canceled claim 5 and added claims 23-27. Independent claim 23 and dependent claims 24-27 are directed to a non-human mammalian model, which is a patentable subject matter. Therefore, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. § 101 be withdrawn.

#### **35 U.S.C. § 112, First Paragraph, Rejection**

Claims 1-9 stand rejected under 35 U.S.C. § 112, first paragraph, for lacking of enablement. This rejection is respectfully traversed.

Claims 1-9 have been canceled and claims 18-27 have been added without prejudice as to patentability. Applicant respectfully submits that the new claims 18-27 are adequately supported by the specification as filed.

Applicant believes that the new claims 18-27 are enabled. First, the new claims 18-27 only encompass non-human mammalian pain models which are produced through non-transgenic methods (emphasis added). That is, the claimed models do not include transgenic animals. Neither are non-mammalian species included in the present invention.

Second, Applicant respectfully submits that it is within the ordinary skill in the art to expand the way of injection of collagen as described in the present specification to injection of a gel substance other than collagen. It is emphasized that in the present invention the substance to be injected around a nerve to generate persistent neurogenic pain models is in the form of gels. It is believed that different gel substances can be handled similarly due to the similar form they are in.

Third, the Examiner states that compression of any nerve will not necessarily result in persistent neurogenic pain citing the reference of Lundborg. Applicant respectfully submits that Lundborg is inappropriately cited. This reference discloses that compression is applied to the median nerve to cause a complete sensory conduction block with little or no pain resulting from the pressure. Applicant believes that such an external compression is indeed traumatic in causing a complete sensory block. With a sensory block there is no pain possible. Whereas in the present invention, compression applied to the nerve is not traumatic and does not cause a complete sensory block.

Fourth, it is known to one of an ordinary skill in the art that peripheral nerves in a mammalian species are physiologically and anatomically similar. It is believed that the methods of altering the tibial nerve and saphenous nerve can be expanded to altering other peripheral nerves. With the examples on alteration of the tibial nerve and saphenous nerve provided in the present application, Applicant believes that no undue experimentation is required to determine how to alter other peripheral nerves to generate persistent neurogenic pain models.

#### 35 U.S.C. § 112, Second Paragraph, Rejection

Claims 1-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is respectfully traversed.

Applicant has canceled claims 1-9 and added new claims 18-27 to overcome the rejection. Therefore, Applicant respectfully requests that the rejection of claims 1-9 under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 102 Rejection

Claim 1 stands rejected under 35 U.S.C. § 102 as being anticipated by Peterson. This rejection is respectfully traversed.

Applicant first draws the Examiner's attention that claim 1 has been canceled and replaced with claim 18 to better define the subject matter which Applicant regards as the invention.

Peterson discloses a human experimental pain model (emphasis added). Specifically, healthy male and female volunteers were recruited and transformed into human experimental pain models using the heat-capsaicin sensitization method. Since capsaicin is known in the art to produce nerve damage to specific fibers, Peterson's method is actually an irritant method and is not trauma free.

In fact, Peterson teaches away from the present invention. First, Peterson does not disclose a non-human mammalian model for persistent neurogenic pain or a method of producing such a model. In contrast, the present invention teaches a non-human mammalian chronic pain model and a method of producing such a non-human pain model. Second, the pain behavior in Peterson's models only lasts 40 minutes and requires rekindling 4 times at 40-minute intervals with heat for five minutes. This pain model does not parallel persistent human chronic pain which usually develops slowly and gradually after the stage of healing and tissue repair and lasts months afterwards. In contrast, the pain behavior in Applicant's pain model lasts over 6 months with only one period of stimulation.

In view of the above remarks, Peterson does not anticipate the present invention as claimed. Accordingly, Applicant respectfully requests that the rejection of claim 1 under 35 U.S.C. § 102 be withdrawn.

Claim 5 stands rejected under 35 U.S.C. § 102 as being anticipated by Lublin. This rejection is respectfully traversed.

Applicant first draws the Examiner's attention that claim 5 has been canceled and replaced with claim 23 to better define the subject matter which Applicant regards as the invention.

Lublin teaches human patients with carpal tunnel syndrome (emphasis added). Lublin does not teach a non-human mammalian model for persistent neurogenic pain, which is the subject matter claimed in the present invention. Thus, Lublin teaches away from the present invention.

In view of the above remarks, Lublin does not anticipate the present invention as claimed. Accordingly, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. § 102 be withdrawn.

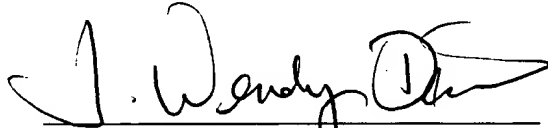
**CONCLUSION**

In view of the amendments and remarks set forth herein, Applicant respectfully submits that the application is in condition for allowance. As such, Applicant respectfully requests that a Notice of Allowance be issued in due course.

Respectfully submitted,

Date:

June 4, 2004

A handwritten signature in black ink, appearing to read "J. Wendy Davis", written over a horizontal line.

J. Wendy Davis, Ph.D.

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